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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,596	01/21/2004	Wilfred Wayne Lutt	14217.1USC1	4255

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EXAMINER
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DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/761,596

Applicant(s)

LAUTT

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Detailed Action***

***Response to Amendment(s)***

The following is responsive to applicant's amendment received Jan. 24, 2005.

Claims 1-8 are cancelled. New claims 14-16 are added. Claims 9-16 are currently pending.

The previous claim objection set forth in paragraph 1 of the office action mailed Sep. 22, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing the previous claim rejections under 35 USC 102(b) and 102(e) as well as the previous claim rejection under 35 USC 103(a) set forth in paragraphs 2-6 of the office action mailed Sep. 22, 2004 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Sep. 22, 2004 with the following additional comment.

***Claim Rejection(s)—35 USC 102***

Applicant argues that neither Klokke-Bethke et al. nor Veronesi et al. disclose a composition containing a nitric oxide agonist, wherein the composition is structurally modified to preferentially release nitric oxide in the liver.

Similarly, neither Adams et al. nor Papandreou et al. nor Salzman et al. disclose a composition containing a nitric oxide donor, wherein the composition is structurally modified to preferentially release nitric oxide in the liver.

Thus, claims 9 and 10 are not anticipated by the prior art of record.

Said arguments have been considered but are not found to be persuasive.

Concerning the limitation “structurally modified to preferentially release nitric oxide in the liver”, at page 8, lines 10-15 of the specification, the limitation “nitric oxide donors and agonists” is described as encompassing a number of compounds such as SIN-1, SNAP, sodium nitrite and nitroprusside. The Examiner respectfully submits that although the references don’t specifically disclose that the nitric oxide donors or agonists are “structurally adapted to preferentially release nitric oxide in the liver”, the references do disclose compositions containing compounds (nitroglycerin, nicorandil, SNAP, sodium nitroprusside, etc.) that are encompassed by the claims. Therefore, the Examiner submits that the prior art of record anticipates Applicant’s claimed compositions. Finally, there are no limitations in the claims, which structurally distinguish the claimed compositions from those disclosed by the prior art.

Concerning newly added claims 14-15, these rejections fall under the previous claim rejections under 35 USC 102(b) and (e). These claims do not contain additional structural limitations and recite intended use. As stated in the office action mailed Sep. 22, 2004, the prior art compositions containing nitric oxide donors or nitric oxide agonists are capable of performing the claimed intended use.

***Claim Rejection(s)—35 USC 103***

Applicant argues that In re Ngai and In re Gulack are misapplied. Specifically, in Ngai and Gulack both the prior art and claimed invention contained instructional material. On the other hand, the prior art of record fails to disclose formulating a kit with instructional material. None of the reference suggests modifying the compositions into a

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kit with instructional material for administering the composition to ameliorate symptoms of insulin resistance. Therefore, one of ordinary skill in the art would not have been motivated to arrive at the claimed invention.

Said arguments have been considered but are not found to be persuasive.

Although, the facts in Ngai and Gulack differ, the test for determining patentability of kit claims is applicable to the claims at issue in the instant application. The test relates to the "functionality" of the printed matter. "Where printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Please see In re Ngai et al., 03-1524 (CAFC 2004) (citing In re Gulack, 217 USPQ 401 (CAFC 1983)). In this case, the instructional material is not functionally related to the nitric oxide donor or agonist compositions because these compositions can function as an active effective drug even in the absence of the instructional material. Therefore, the Examiner respectfully maintains that the instructional material does not patentably distinguish the claimed compositions over the prior art. Finally, the instructional material describing instruction for using the nitric oxide donor or agonist compositions merely teaches a new use for an existing product and does not impart patentability.

With respect to claim 16, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a composition containing a combination of a nitric oxide donor and a nitric oxide agonist because one of ordinary skill in the art would reasonably expect the additive effect of the two compounds to effectively increase production or release of nitric oxide in a patient in need thereof.

***New Ground(s) of Rejection***

***Claim Rejection(s)—35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 16 recites a limitation where the kit of claim 11 comprises "a nitric oxide donor and a nitric oxide agonist." However, there is no support in applicant's specification for a combination composition comprising a nitric oxide donor and a nitric oxide agonist. The specification, on the other hand, describes compositions, which contain either a nitric oxide donor or a nitric oxide agonist. Therefore, one of ordinary skill in the art would not have concluded that applicant was in possession of the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "said insulin sensitivity" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "a nitric oxide donor and a nitric oxide agonist" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Conclusion***

Claims 9-16 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number

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is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

May 15, 2005



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